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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 09/159,172 | 09/23/1998 | FRANCIS A. ENNIS | UMMC98-13 | 4830 |
| 21005 | 7590 | 10/28/2003 | EXAMINER | |
| HAMILTON, BROOK, SMITH & REYNOLDS, P.C. 530 VIRGINIA ROAD P.O. BOX 9133 CONCORD, MA 01742-9133 | | | SAUNDERS, DAVID A | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1644 | |
| DATE MAILED: 10/28/2003 | | | | |

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

| | | | |
|-----------------|----------|----------------|---------------------|
| Application No. | 159,172 | Applicant(s) | ENNIS <i>et al.</i> |
| Examiner | SAUNDERS | Group Art Unit | 1644 |

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

Responsive to communication(s) filed on 4/8/03

This action is FINAL.

Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

Claim(s) 24-35 is/are pending in the application.

Of the above claim(s) _____ is/are withdrawn from consideration.

Claim(s) _____ is/are allowed.

Claim(s) 24-35 is/are rejected.

Claim(s) _____ is/are objected to.

Claim(s) _____ are subject to restriction or election requirement.

Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The proposed drawing correction, filed on _____ is approved disapproved.

The drawing(s) filed on _____ is/are objected to by the Examiner.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All Some* None of the CERTIFIED copies of the priority documents have been

received.

received in Application No. (Series Code/Serial Number) _____.

received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

Attachment(s)

Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

Interview Summary, PTO-413

Notice of Reference(s) Cited, PTO-892

Notice of Informal Patent Application, PTO-152

Notice of Draftsperson's Patent Drawing Review, PTO-948

Other _____

Office Action Summary

The amendment of 4/8/03 has been entered. Claims 24-35 are pending and under examination.

The following correction has been entered in the previous Office action (Paper 19):

At page 2, line 12 deleted "grew" and inserted therefor -group--.

This change has been entered in red ink and initialed and dated by the examiner.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Newly presented claims 24, 28 and 32, corresponding to previously presented claims 1, 7 and 11, have overcome previously stated rejections pertaining to these claims under 35 U.S.C. 112, first and second paragraphs.

New rejections under 112 follow.

Claim 35 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 35 contains new matter.

The claim is interpreted as literally reading, in step (a), that one contacts APCs within a single culture with two or more distinct vaccine compositions.

Applicant has urged that page 8, 13-23 support this claim; however, the examiner finds that this disclosure recites "the vaccine composition" in the singular, rather than "two or more."

Claim 35 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter, which was not described in the specification in such a way as to enable one skilled in the relevant art to make and/or use the invention. Claim 35 fails to enable the selecting of "the vaccine composition is possessing an optimal response" as required in step (C).

Since the claim is interpreted as literally reading, in step (a), that one contacts APCs within a single culture with two or more distinct vaccine compositions; the examiner fails to see how one can select which particular vaccine composition, among the two or more, is the one which has stimulated the T-cell response. Unless each vaccine composition is separately cultured with APCs, there is no way that one can determine which particular vaccine composition is the one that provides an "optimal response".

Applicant's amendment has overcome the prior art of record.

Applicant's amendment has necessitated the following newly stated double patenting rejection.

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 24-32 and 35 are rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-9 and 12 of prior U.S. Patent No. 6,627,407. This is a double patenting rejection.

Instant claims 24, 26-29 and 32 correspond to issued claims 1, 3-6 and 7 respectively.

Instant claim 25 corresponds to issued claim 12.

Instant claims 30 and 31 correspond to issued claims 9 and 8, respectively.

Instant claim 35 corresponds to issued claim 2.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 33-34 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 7 and 9-

11 of U.S. Patent No. 6,627,407. Although the conflicting claims are not identical, they are not patentably distinct from each other because instant claims 33-34, but for their dependencies, recite the same features as issued claims 10-11. It would have been obvious, from the issued claims to have also recited these features as dependency from issued claim 7 (as instant claims 33-34 read from their dependency from issued claim 32), as well as from issued claims 1 and 9, (as issued claims 10-11 read in their recited dependencies). One of skill would have fully expected that the features of these dependent claims would be operative in either the method of issued claims 1 and 7 (Instant claims 24 and 32), since essentially the same steps are involved and the same mechanisms of T-cell response to APC presented antigens are involved in each case.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will

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the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A. Saunders, Ph.D., whose telephone number is (703) 308-3976. The examiner can normally be reached on Monday-Thursday from 8:00 a.m. to 5:30 p.m. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan, can be reached on (703) 308-3973. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

D. A. Saunders:jmr
October 21, 2003

David A. Saunders
DAVID SAUNDERS
PRIMARY EXAMINER
ART UNIT 182 1644